UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,548	08/08/2001	Shoukat Dedhar	KINE001CIP4	5127

24353 7590 06/02/2005

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUN -2 2005

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94303

In re Application of
Arthur et al
Serial No. : 09/925,548
Filed : August 8, 2001
Attorney Ref No. : KINE-001CIP4

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.181, filed on February 16, 2004, to review the restriction requirement. The delay in acting on this petition is regretted.

BACKGROUND

A review of the file history shows that the application was filed on August 8, 2001 with 7 claims and a sequence listing with 97 sequences

A requirement for restriction was mailed to applicants on 1/29/2003. In this paper the examiner required the restriction of the 7 claims into two different groups, Group I, drawn to an oligonucleotide and Group II, drawn to a method of inhibiting expression of integrin linked kinase using an oligonucleotide. The examiner further required that in addition to the above election to one of the two groups, applicants should additionally elect a single SEQ ID No for examination.

Applicants responded with an election of Group I and SEQ ID NO: 16, with traverse, on 3/4/2003. Following the election, on 5/9/2003, applicants submitted a new sequence listing with 99 sequences. The new sequence listing appeared to be identical to that previously submitted in the application with the exception that two additional sequences, a new SEQ ID NO: 1 and a new SEQ ID NO: 2, which correspond to the full length integrin-linked kinase gene and its encoded protein were added to the previously submitted 97 sequences.

In response to the election, the examiner acknowledged the election of Group I, claims 1-4 and SEQ ID NO: 16 and further considered the traversal and found applicants arguments non-persuasive and made the restriction requirement FINAL in the paper of 5/29/2003. The examiner further acknowledged the newly submitted sequence listing and stated that "Since the SEQ ID Nos: 13-109 have been amended to read as SEQ ID Nos 3-99, the elected SEQ ID No. 16 corresponds to SEQ ID No. 6 of the new sequence listing and thus claims 1-4 and SEQ ID

NO: 6 are under consideration." (Examiner inadvertently assumed that elected SEQ ID NO: 16 was equal to new SEQ ID NO: 6, applicants did not clarify that SEQ ID NO: 16 is equal to new SEQ ID NO: 18).

A first office action on the merits was also mailed as a part of this same communication, in which claims 1-4 were rejected under 35 USC 112 2nd paragraph and claims 1 and 2 were rejected under 35 USC 102(a) and (b).

On 8/16/2004, the examiner mailed a second non-final office action in which the only pending claims, claims 3 and 4, were objected to because they encompassed non-elected subject matter (i.e. SEQ ID Nos. 3-5 and 7-99). The examiner again stated that the elected subject matter is SEQ ID NO: 6 and further noted that an oligonucleotide comprising SEQ ID No. 6 is free of the prior art.

In response to the non-final rejection of 8/16/2004, applicants responded with the instant petition and accompanying arguments in which applicants acknowledge the examiner's previous statement that an oligonucleotide comprising SEQ ID NO:6 is free of the prior art and in condition for allowance.

DISCUSSION

The application, file history and petition under 37 C.F.R. 1.181, to request review of the restriction requirement has been considered.

Prior to the discussion of the issue of review of the restriction requirement, the record should be made clear. Applicants' election of the subject matter of Group I, claims 1-4 and SEQ ID NO: 16 has been and is acknowledged. At the time of election, this sequence is "ccacagcaga gcggccctc". Following the amendment of the sequence listing made on 5/9/2003, SEQ ID NO: 16, "ccacagcaga gcggccctc", now corresponds to SEQ ID NO: 18, **not** SEQ ID NO: 6. Thus the original election of Group I and SEQ ID NO: 16 now corresponds to Group I and SEQ ID NO: 18.

Applicants' petition under 37 C.F.R. 1.181 to review the restriction requirement and request rejoinder of the oligonucleotide sequences set forth in claims 3 and 4.

Applicants submit that all of the presently claimed oligonucleotide sequences are short, defined fragments of the larger sequence, SEQ ID NO: 1 and that SEQ ID NO: 1 is a cDNA derived from an mRNA transcript of the integrin linked kinase (ILK). Based on this applicants submit that the oligonucleotide sequences are therefore all related, and that the sequences set forth in claims 3 and 4 share a common function and are related as being fragments of a single entity that encodes a single polypeptide.

The claims as amended 6/10/2004 read as follows:

3. An oligonucleotide comprising at least 18 nucleotide and having a sequence selected from the group consisting of SEQ ID NO: 3 to SEQ ID NO: 99.
4. The oligonucleotide according to claim 3, and a pharmaceutically acceptable carrier.

Applicants' complete argument is acknowledged, however, found non-persuasive.

The previous restriction required that by statute, under 35 U.S.C. 121, applicants elect a single disclosed SEQ ID No, even though this requirement is traversed. Oligonucleotides comprising these "sequences", while not indicated at the time, are patentably distinct, each from the other, because of their materially different nucleic acid sequences. It is noted that SEQ ID NOs: 3-99 are non-overlapping 18 and 19 nucleotide long antisense fragments of SEQ ID NO: 1, a 1789 bp cDNA that encodes the integrin linked kinase. There is not generic linking claim which encompasses the oligonucleotides.

Claim 3 recites an oligonucleotide comprising the various nucleic acid sequences listed in the alternative. Claim 3 could be re-written as a series of dependent claims that capture the full scope of claim 3, without loss or overlap of scope of the claimed invention.

Claims which recite products listed in the alternative may be eligible for election of species practice. MPEP 803.02 states:

> Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Applicants are correct that if the inventions which are claimed in the alternative qualified for Markush practice they would be examined according to 803.02. But this is not required for the following reasons. Applicants assert that the 97 sequences recited in claims 3 and 4 share a common utility. However this argument is not commensurate in scope with claims which fail to require any common function. Further, the 97 oligonucleotides do not appear to share any substantial structural feature one with another, let alone any substantial feature disclosed as being essential to that utility. An alignment of elected SEQ ID NO: 18 (ccacagcaga gcggccctc) with SEQ ID NOs 3-17 and 19-99 (For example randomly selected SEQ ID NO: 3, ccttctccgg ggaactccc, SEQ ID NO: 7, gcctgaggac tgtggagtg) shows no apparent shared structure between the individual sequences or between groups of the individual sequences. While the molecules may hybridize to the common structure of the gene of SEQ ID NO: 1, it is noted that SEQ ID NO: 1 is 1789 nucleotides long, whereas the oligonucleotides are 18-19 -mers. Fragments

derived from a full length molecule do not per se share a common structure with the full length molecule or with one another. Further the oligonucleotides do not share any common structure essential for common utility with the full length gene, nor with each other. SEQ ID NO: 1 encodes an integrin linked kinase protein, a utility that the short oligonucleotides 3-99 are not required to possess.

It is thus proper for the Office to set forth a restriction requirement to a single invention. Because the oligonucleotides lack "unity of invention", per 803.02, election of species practice is not required.

The inventions are distinct, each from the other because of the following reasons:

The inventions corresponding to SEQ ID NOs: 3-99 are related as each are non-overlapping 18 and 19 nucleotide long antisense fragments of SEQ ID NO: 1.

Applicants' attention is directed to MPEP 803 which states:

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

The inventions as claimed (SEQ ID NOs: 3-99) are distinct. The inventions do not require the related feature of hybridizing to SEQ ID NO: 1 and other sequences could be antisense fragments of SEQ ID NO: 1.

The oligonucleotides comprising SEQ ID NOs: 3-99 are not required by the claims to have a shared common utility. Further the oligonucleotides are not claimed in terms of a linking claim which encompasses the inventions by a generic concept.

A proper search and examination of more then one of the identified oligonucleotides (i.e. SEQ ID NOs: 3-99) would result in a serious burden on the examiner by virtue that each of the different SEQ ID NOs: 3-99 denote structurally different nucleic acid sequences comprising different functions. As such a search of the different inventions involves different searches of various nucleic acid databases as well as completely different text searches, depending on the elected invention.

Because these inventions are distinct for the reasons given above and the search required for each of the different nucleic acid sequences corresponding to SEQ ID NOs: 3-99 are different, restriction for examination purposes as indicated is proper.

Applicants argue that the examination of more than one sequence would not be an undue burden on the examiner on the basis that "...to aid the biotechnology industry in protecting its

intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et. seq* and permit a reasonable number of sequences to be claimed in a single application...normally ten sequences..."

Applicants reference to the U.S. Patent and Trademark Office policy regarding the examination of patent applications that claim large numbers of nucleotide sequences in the Official Gazette, 1192 O.G. 68 (November 19, 1996) is acknowledged, however, not found persuasive on the basis that this policy regarding the partial waiving of the requirements of 37 CFR 1.141 is such that it will permit a reasonable number of nucleotide sequences to be claimed in a single application. Under the policy, up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction. The waiver is permissive and not a requirement. The present restriction requirement conforms with this policy as it has required that the application be restricted to a single sequence. Applicants are reminded that one is within the range of up to ten.

Further, applicants' request that, should the above discussed rejoinder of all 97 SEQ ID NOs; not be granted, ten of the oligonucleotide sequences be rejoined in the present claims is incomplete, as applicants have not provided a list of 10 sequences to be searched. Applicants must make their own election as per MPEP 818.03(e) and the Office can not determine which ten sequences should be rejoined if such were to occur.

Not withstanding the above discussion, as applicants elected SEQ ID NO: 16, now SEQ ID NO: 18 and during the course of examination a different invention, an oligonucleotide comprising SEQ ID NO: 6 has been determined to be free of the prior art, it is determined that applicants should receive examination of the subject matter of oligonucleotides comprising SEQ ID NO: 18 and SEQ ID NO: 6.

Accordingly the restriction requirement between original oligonucleotide comprising SEQ ID NO: 16 (now SEQ ID NO: 18) and oligonucleotide comprising SEQ ID NO: 6 is hereby withdrawn.

DECISION

For these reasons, the petition under 37 C.F.R. 1.144 to request review of the restriction requirement and request rejoinder of the oligonucleotide sequences set forth in claims 3 and 4 is **GRANTED-IN-PART** as follows.

The request to have all 97 oligonucleotides examine together is **DENIED.**

The incomplete request to have 10 unspecific oligonucleotides examined together is **DISMISSED**.

In view of the prosecution history, rejoinder of the oligonucleotide comprising SEQ ID No 6 and SEQ ID No 18 (as numbered and described by the current sequence listing) is **GRANTED.**

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner to take appropriate action as a result of this petition decision and to consider the amendments and arguments filed by applicants on 2/16/2005.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

Jasemine C. Chambers

Jasemine Chambers
Director, Technology Center 1600